

REMARKS/ARGUMENTS

Attorney Docket Number

Applicant would like to inform the Examiner that it is represented by new counsel in the present matter. As such, Applicant respectfully requests that the Attorney Docket Number for the present case be changed from "3295-0024-0CONT" to "OHI 1717-096." Applicant also respectfully requests that the Examiner use this new docket number in all future correspondence relating to the present application. Applicant would also like to inform the Examiner that a change in Power of Attorney was submitted to the PTO several months ago with respect to the present application, but appears to not yet have been recorded.

Information Disclosure Statement

The Examiner's rejection of the foreign language document citations included in the June 04, 2004 Information Disclosure Statement is acknowledged.

In the Claims:

Claims 75-78, 80, 85, 88-89, 92-94, 96, 99, 102-103, 106-107, 110-111, 114-115 and 118-165 remain pending in the present application. Claims 75-77, 80, 85, 88, 89, 92-94, 96, 99, 102, 103, 106, 107, 110, 111, 114, 115, and 118-120 have been amended. Claims 86, 90 and 91 have been canceled in the present response. Claims 124-165 have been added. No new material has been added.

Support for Claim Amendments

Support for the subject matter of the claims, as amended and added, may be found at various locations in the present application, as well as in U.S. Patent Application No. 08/611,306 (now U.S. Patent No. 5,830,237), to which the present application claims priority.

With respect to the ability of the polymeric material of the present invention to provide an air-tight seal with an amputation stump: support can be found at least at page 2, line 21 to page 3, line 4 of the present application, as well as at least column 1, lines 48-58 of the '237 patent, wherein breathable (porous) stump socks are differentiated from polymeric socks (coverings) - such as those of the present invention. Further, the inherent sealing capabilities of such a polymeric material would be apparent to one skilled in the art.

With respect to the cushion liner being thicker at its closed end than at its open end: support can be found at least at page 13, lines 8-14 and 21-23 of the present application, as well as at least at column 5, line 67 to column 6, line 6; and column 6, lines 14-15 of the '237 patent.

With respect to the cushion liner having an uneven distribution of polymeric cushioning material that results in a thinner posterior middle and upper portion, and a thicker distal anterior-medial and anterior-lateral portion: support can be found at least in Figure 7 and at page 13, lines 14-21 of the present application, as well as at least in Figures 7a-7b and column 6, lines 6-13 of the '237 patent.

With respect to the cushion liner being coated completely on the inside thereof with polymeric material: support can be found at least at page 16, line 24 to page 17,

line 1; page 25, lines 1-10; and page 26, lines 16-18 of the present application, as well as at least in Figures 5-9 and at column 7, lines 31-35; column 10, lines 51-62; and column 11, lines 25-27 of the '237 patent.

With respect to the cushion liner including mineral oil: support can be found at least at page 8, lines 15-18; page 10, lines 21-22; page 10, line 25 to page 11, line 2; page 11, line 26 to page 12, line 6; page 12, lines 11-12; page 24, lines 14-15; and page 26, lines 10-11 of the present application, as well as at least at column 4, lines 4-7 and lines 66-67; column 5, lines 2-7 and 31-38; column 10, lines 37-38; and column 11, lines 19-20 of the '237 patent.

With respect to the cushion liner including a biocide: support can be found at least at page 8, lines 15-18; and page 26, lines 13-15 of the present application, as well as at least at column 4, lines 4-7; and column 11, lines 22-24 of the '237 patent.

With respect to the cushion liner including a vitamin: support can be found at least at page 8, lines 15-18; and page 26, lines 5-6 of the present application, as well as at least at column 4, lines 4-7; and column 11, lines 14-15 of the '237 patent.

With respect to the cushion liner having a recessed Achilles configuration: support can be found at least in Figure 7 and at page 8, lines 6-14; page 9, line 1-4; page 13, lines 4-6; page 22, line 22 to page 23, line 12; page 26, lines 16-26; and page 27, lines 11-16 of the present application, as well as at least in Figure 7a and at column 3, lines 62-67; column 4, lines 16-19; column 5, lines 63-65; column 9, line 57 to column 10, line 7; column 11, lines 25-33; and column 11, lines 46-51 of the '237 patent.

With respect to the cushion liner including a docking means: support can be found at least in Figure 9 and at page 6, line 24 to page 7, line 1; and page 15, lines 3-

12 of the present application, as well as at least in Figure 9 and at column 3, lines 25-29; and column 6, lines 50-59 of the '237 patent.

With respect to the cushion liner including a docking means that is molded to the fabric portion of the liner: support can be found at least in Figure 9 and at page 7, lines 1-2; and page 15, lines 7-10 of the present application, as well as at least in Figure 9 and at column 3, lines 29-30; and column 6, lines 54-57 of the '237 patent.

With respect to the cushion liner having a length of 10-25 inches: support can be found at least at page 15, lines 25-26; and page 32, lines 16-17 of the present application, as well as at least at column 7, lines 5-6; and column 13, lines 47-48 of the '237 patent.

Rejection of Claim 86 Under 35 U.S.C. § 112

The Examiner rejected claim 86 under 35 U.S.C. § 112, second paragraph, as being indefinite for depending from a canceled claim. Applicant has canceled claim 86, thereby rendering this rejection moot.

Rejection of Claims Under 35 U.S.C. § 112

The Examiner rejected claims 75-78, 80, 85-86, 88-89, 92-94, 96, 99, 102-103, 106-107, 110-111, 114-115 and 118-121 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not adequately described in the specification. More specifically, the Examiner asserts that the terms "non-porous" and "non-porosity" are not supported by the specification. Applicant has amended claims 75-77, 80, 85, 88, 89, 92-94, 96, 99, 102, 103, 106, 107, 110, 111, 114, 115, and 118-120 to more clearly describe the subject matter recited therein. All references to a "non-porous polymeric

cushioning material” have been replaced with “a polymeric cushioning material ‘capable of forming an airtight seal’...” Applicant submits that the amended claim language is fully supported by the present specification, and comports with the allowed claim language of U.S. Patent No. 6,406,499 and the claim language of U.S. Patent Application No. 09/418,505, for which a Notice of Allowance was mailed on March 01, 2005. As such, Applicant respectfully submits that the Examiner’s 35 U.S.C. § 112 rejection of claims 75-78, 80, 85-86, 88-89, 92-94, 96, 99, 102-103, 106-107, 110-111, 114-115 and 118-121 has been rendered moot and may, therefore, be properly withdrawn.

Apparent Rejections With Respect to Previously Cited Prior Art

Although the Examiner has not issued any prior art rejections of the pending claims in the present Office Action, it appears that such rejections were made in the Office Action of August 19, 2003. Although the present Office Action contains only 35 U.S.C. § 112 rejections, in an attempt to expedite allowance of the present application, Applicant would like to briefly distinguish the present form of the claims over the teachings of the references previously cited as prior art by the Examiner.

Applicant has amended the presently pending claims to recite that the polymeric cushioning material of the cushion liners “is capable of forming an air-tight seal with the amputation stump when said liner is worn.” Applicant has deleted any reference to the polymeric cushioning material being “non-porous,” which language was rejected by the Examiner. Applicant respectfully submits that the claims also now clearly recite that the polymeric cushioning material resides only on an inside surface of a fabric covering, and

that it is the polymeric cushioning material that is in contact with the skin of the amputation stump when the liner is worn - not the fabric covering. Applicant also submits that the language reciting that the polymeric cushioning material "is capable of forming an air-tight seal with the amputation stump" better comports with the allowed claim language of U.S. Patent No. 6,406,499, which is related to the present application.

Applicant submits that none of GB 2 213 380 A, US 4,635,626 (Lerman), or SU 1739990 A1, which to Applicant's knowledge were the references cited in the August 19, 2003 Office Action, teach a cushion liner as recited in the rejected claims. Applicant submits that GB 2 213 380 A is not capable of forming an air-tight seal with an amputation stump because it is specifically stated therein that the cover material is comprised of a PTFE material that is capable of transmitting water vapor and gases. Hence, a liner made from such a material would be capable of transmitting air - a gas. As further evidence that the cover of GB 2 213 380 A cannot form an air-tight seal, it is suggested that a secondary rim must be fitted to the cover to aid in its retention on the amputation stump.

Further, the cover of GB 2 213 380 A does not appear to be a cushion liner. Based on the selected cover material and a suggested thickness of only 0.0035 inches, Applicant respectfully submits that the cover would provide for virtually no cushioning. In fact, it appears that a wool sock having a thickness that is multiple times that of the cover must be simultaneously worn to assist in cushioning the amputation stump.

Additionally, the goal of GB 2 213 380 A appears to be a cover that wicks perspiration, in the form of water vapor, to the outside of the cover where it can be absorbed by the wool sock. This is opposite to the function of the cushion liner of the

present invention. Rather, the cushion liner of the present invention is designed to prevent the permeation of perspiration through the liner. It is preferred that any perspiration be contained by the polymeric cushioning material, thereby ensuring that the exterior of the liner remains dry.

The Lerman reference teaches two variations of a prosthetic stocking (stump sock): a temporary post-operative stump sock, and a permanent stump sock. However, as a result of the materials used in Lerman, both stump socks are porous to both air and water (and other gases and fluids) and, consequently, are incapable of forming an air-tight seal with the limb of a wearer. While the temporary stump sock and permanent stump sock may have slightly different constructions, it is clear that the main objective of both designs is to allow air and/or other fluids to easily pass therethrough. In fact, it is particularly stated that the breathability of the temporary stump sock base material not only ensures good air circulation to the stump, but also facilitates the dissipation of heat and the absorption of fluids during the healing process.

In contrast, a cushion liner, as recited in the present claims, is not, and cannot be, porous to air and water - as are the stump socks described in Lerman. If the polymeric material of the present invention were able to "breathe," as does the material in Lerman, an air-tight seal could never be formed thereby.

It is noted by Applicant that Lerman does mention the possible use of neoprene rubber as the base layer of the composite used to make the permanent stump sock. However, it is expressly stated that such a material is disfavored due to its closed-cell composition. (See column 5, lines 21-23). In addition, even if a closed-cell neoprene rubber were used as the base layer in Lerman, it is still required that its inner surface

have a fabric layer adhered thereto. (See column 5, lines 27-29; and Fig. 7). As such, even this theoretical, but disfavored embodiment of the Lerman stump sock, fails to teach the cushion liner as claimed in the present application.

With respect to the SU 1739990 A1 reference, Applicant respectfully submits that the liner taught thereby is considerably different than a cushion liner of the rejected claims. The cushion liner of the present invention includes a polymeric cushioning material that is disposed on only the inside surface of a fabric cover. The polymeric cushioning material is capable of forming an air-tight seal with the amputation stump, and it is the polymeric cushioning material that is in contact with the skin of the amputation stump when the liner is worn. In contrast the liner of SU 1739990 A1 consists of an inner and outer fabric layer, between which is disposed one or more cushioning pads provided to protect the distal end of the amputation stump as well as one or more bony prominences on the amputation stump.

Consequently, SU 1739990 A1 does not teach a liner having a polymeric cushioning material coated seamlessly to only the inside surface of a fabric cover, or to any cover. SU 1739990 A1 also fails to teach a liner wherein a polymeric cushioning material is in contact with the skin of an amputation stump when the liner is worn by a user. Rather, it is the inner fabric layer that is in contact with the amputation stump when the SU 1739990 A1 liner is worn.

The SU 1739990 A1 reference further fails to teach or suggest that the cushioning material used therein is capable of forming an air-tight seal with an amputation stump when the liner is worn. And, even if the cushioning material of the SU

1739990 A1 liner had such an ability, no such air-tight seal could be formed because the cushioning material is separated from the amputation stump by a layer of fabric.

Therefore, in light of these significant differences, Applicant respectfully submits that the GB 2 213 380 A, Lerman, and SU 1739990 A1 references cannot support a rejection of the presently pending claims. Consequently, Applicant respectfully requests that the Examiner pass the presently pending claims, as amended, to issuance.

CONCLUSION

Applicant has amended claims 75-77, 80, 85, 88, 89, 92-94, 96, 99, 102, 103, 106, 107, 110, 111, 114, 115, and 118-120, has canceled claims 86, 90 and 91, and has added new claims 124-165. Applicant has also distinguished the subject matter of the present invention over the teachings of the references previously cited as prior art by the Examiner.

Therefore, Applicant respectfully submits that the present application is now in condition for allowance, and entry of the present amendment and allowance of the application as amended is earnestly requested. If, however, the Examiner maintains his rejection, entry of the present amendment is respectfully requested as reducing the number of issues and placing this application in better condition for appeal.

Telephone inquiry to the undersigned in order to clarify or otherwise expedite prosecution of the present application is encouraged.

Respectfully submitted,

Date: 5-26-05

By:

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